



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,847	08/22/2003	William E. Klunk	076333-0323	8143
22428	7590	08/11/2006	EXAMINER JONES, DAMERON LEVEST	
FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			ART UNIT 1618	PAPER NUMBER

DATE MAILED: 08/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/645,847	KLUNK ET AL.	
	Examiner	Art Unit	
	D. L. Jones	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 18 May 2006. ✓ 8/20/04
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 4-7, 11-13 and 15-27 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-3, 8-10, and 14 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 8/20/04
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

ACKNOWLEDGMENTS

1. The declaration under 37 CFR 1.132 filed 5/18/06 is sufficient to overcome the rejection of claims 1-3 and 14 based upon 35 USC 103(a).

Note: Claims 1-27 are pending.

RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENTS

2. The Applicant's arguments filed 5/18/06 to the rejection of claims 1-3, 8-10, and 14 made by the Examiner under 35 USC 103 and/or double patenting have been fully considered and deemed persuasive-in-part for the reasons set forth below.

Double Patenting Rejection

The provisional rejection of claims 1-3, 8-10, and 14 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 24 of copending Application No. 10/388,173 is MAINTAINED for reasons of record in the office action mailed 1/26/06.

Note: It is duly noted that Applicant has requested that the PTO hold the rejection in abeyance until such time as the PTO indicates allowable subject matter.

103 Rejection

The 103(a) rejection is WITHDRAWN because Applicant has submitted a declaration under 37CFR 1.132 to overcome the rejection.

ELECTION OF SPECIES INFORMATION

3. The Examiner once again acknowledges Applicant's election of Group I, claims 1-14 in the reply filed on 10/31/05. In addition, Applicant elected the species of

Example 4, page 22, in the specification. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Thus, the restriction requirement is deemed proper and is made FINAL.

Notes: (1) Initially, Applicant's elected species was searched. However, since no prior art was found which could be used against the claims, (2) the search was expanded to the compound of Formula I wherein R1 is OH; R2 is hydrogen; R3 is hydrogen; and R4 is $^{11}\text{CH}_3$. While art was found to reject the species wherein R1 is OH; R2 is hydrogen; R3 is hydrogen; and R4 is $^{11}\text{CH}_3$, Applicant submitted a declaration under 37 CFR 1.132 to overcome the rejection. (3) As a result, the search has been further expanded to the compound of Formula I wherein R1 is CH3; R2 is hydrogen; R3 is hydrogen; and R4 is $^{11}\text{CH}_3$. The search was not further expanded because prior art was found which could be used to reject the claims.

WITHDRAWN CLAIMS

4. Claims 4-7, 11-13, and 15-27 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention/species.

NEW GROUNDS OF REJECTION

102 Rejection

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1618

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-3 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Klunk et al (Life Sciences, August 17, 2001, Vol. 69, No. 13, pages 1471-1484).

Klunk et al disclose uncharged thioflavin-T derivatives that bind to amyloid beta protein with high affinity and readily enter the brain. In particular, Applicant discloses the species N-(methyl-11C)-4-(6-methyl-2-benzothiazolyl)-benzenamine (see page 1472, Figure 1, the {N-methyl-11C]6-Me-BTA-1 structure) that fulfills the requirements of the instant invention when R1 is CH3; R2 is hydrogen; R3 is hydrogen; and R4 is $^{11}\text{CH}_3$. Thus, both Applicant and Klunk et al disclose species encompassed by Formula I of the instant invention.

103 Rejections

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-3 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klunk et al (Life Sciences, August 17, 2001, Vol. 69, No. 13, pages 1471-1484).

Klunk et al (see discussion above) discloses a species encompassed by Formula I of the instant invention wherein when R1 is CH3; R2 is hydrogen; R3 is hydrogen; and R4 is $^{11}\text{CH}_3$. However, Klunk et al fail to disclose various obvious

Art Unit: 1618

modifications to the structure as set forth below: (1) Species wherein R1 is CH₃; R2 is hydrogen; **R3 is CH₃**; and R4 is ¹¹CH₃ or (2) R1 is CH₃; **R2 is CH₃**; R3 is hydrogen; and R4 is ¹¹CH₃. In both of these instances, it would have been obvious to replace a hydrogen group with methyl (CH₃). In particular, it is well established that the substitution of methyl for hydrogen on a known compound is not a patentable modification absent unexpected or unobvious results (*In re Woods*, 582 F.2d 638, 199 USPQ 137 (CCPA 1978)). (3) Species wherein **R1 is C₂-C₆ alkyl**; R2 is hydrogen; R3 is hydrogen; and R4 is ¹¹CH₃ and (4) R1 is CH₃; R2 is hydrogen; R3 is hydrogen; and R4 is ¹¹CH₂-(CH₂)₀₋₄-CH₃ (this generates a ¹¹C₁-C₆ alkyl group). In particular, a skilled practitioner in the art would recognize a homologous series as a family of chemically related compounds that vary from member to member by one or more CH₂ group. Hence, a skilled practitioner would recognize that the characteristics normally possessed by members of a homologous series are principally the same, varying gradually from member to member. As a result, chemist knowing the properties of one member of a series would in general know what to expect in adjacent members so that a mere difference in degree is not the marked superiority which will ordinarily remove the unpatentability of adjacent homologues of old substances.

COMMENTS/NOTES

9. Claims 1, 8-10, and 14 are allowable over the elected species only and the species of Formula I wherein R1 is OH; R2 is hydrogen; R3 is hydrogen; and R4 is ¹¹CH₃; however, Applicant MUST address and overcome the double patenting rejection above. In particular, the claims are distinguished over the prior art of record because

Art Unit: 1618

the prior art neither anticipates nor renders obvious a compound having the limitations of the elected species.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

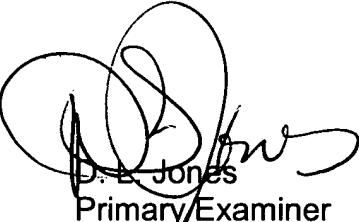
Note: It is duly noted that Applicant submitted a declaration under 37 CFR 1.132 to overcome the previously cited art.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Art Unit: 1618

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D.L. Jones
Primary Examiner
Art Unit 1618

August 7, 2006